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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
UTSD:872US

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Typed or printed name

Application Number	Filed
10688058	October 17, 2003
First Named Inventor	
Kathryn Sykes	
Art Unit	**Examiner**
1645	Rodney Swartz

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 57,423.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

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512-536-5654
Telephone number

December 22, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR 10/688,058

I. The Anticipation Rejection Over Choi (WO 98/59071) is Legally Unsupported

The Examiner's rejection of claims 48 and 88-91 as anticipated by Choi et al. (WO 98/59071) is legally unsupported; a claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled.

Mere naming or description of the subject matter in a reference is insufficient if it cannot be produced without undue experimentation. MPEP § 2131.01. Choi appears to describe a *B. burgdorferi* sequencing project. While Choi discloses hundreds of sequences reportedly obtained from *B. burgdorferi*, it fails to disclose a single example where even one of these sequences was used to elicit an immune response in an animal. Choi has done nothing more than venture a guess that some of the hundreds of *B. Burgdorferi* genes or gene fragments that were sequenced and listed in Table 1 would be useful antigens. This is analogous to a "needle-in-the-haystack" approach. Courts have found no anticipation from these types of disclosures. *See Ex parte Garvey*, 41 U.S.P.Q. 583 (Pat & Trademark Office Bd. App. 1939); *see also In re Luvisi*, 342 F.2d 102 (C.C.P.A. 1965); *Ex parte Frey*, 90 U.S.P.Q 383 (Pat & Trademark Office Bd. App. 1946).

Moreover, as described in the present specification, there have been difficulties associated with immunization against *Borrelia*. For example, antibodies against a number of *B. burgdorferi* antigens have been found to cross-react with host nerve cell axons, synovial cells, hepatocytes, and cardiac muscle proteins (Specification, p. 7, ln. 12-14). Thus, making whole-cell vaccines or vaccines with certain cross-reactive antigens undesirable. The concern of vaccine-induced autoimmunity has focused the development of a vaccine for human Lyme disease on a subunit rather than whole-cell design (Specification, p. 7, ln. 16-18). However, only one FDA licensed vaccine against Borrelia (LYMErix), which is comprised of recombinant

OspA, has been developed (Specification, p. 7, ln. 24). LYMErix was eventually pulled from the market (Specification, p. 8, ln. 30 to p. 9, ln. 2).

The disclosure in Choi is insufficient to enable the presently claimed vaccine, particularly given the art-recognized challenges associated with identifying effective *Borrelia* antigens that do not induce an autoimmune reaction in the host. Appellants, therefore, request the withdrawal of this rejection.

II. The Indefiniteness Rejection is Legally Unsupported

The rejection of claims 48 and 88-91 is improper. The Examiner asserts that claim 48 was amended such that it is now drawn to a non-elected invention. The amendment to claim 48, however, merely involved re-writing the claim in independent form by incorporating the language of claims 31 and 44 from which claim 48 previously depended. Claims 31, 44, and 48 were all included in the Group II invention according to the Restriction Requirement dated June 24, 2005. Accordingly, the present rejection is improper.